EXHIBIT 34

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL NO. 1456**
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO U.S. ex rel. Ven-A-Care of the Florida Keys, Inc., Zachary T. Bentley , and T. Mark Jones v. Abbott Laboratories, Inc., No. 07-CV-11618-PBS	**Judge Patti B. Saris**
	Magistrate Judge Marianne B. Bowler

EXPERT REPORT OF STEVEN J. YOUNG

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I. Qualifications and Compensation

1) I have been a consultant to the health care industry for approximately twenty five years. I have substantial experience with health insurance reimbursement, pharmaceutical pricing and the related distribution channels. My Curriculum Vitae and listing of testimony is attached as Exhibit 1.

2) I have substantial experience related to pharmaceutical manufacturer pricing for both branded and generic drugs. I have worked with pharmaceutical companies in performing detailed analyses of their pricing, chargebacks, and rebate data.

3) I have advised clients in various industries that sell commercial products to the government, including furniture, security equipment, durable medical equipment, secure communications systems, pharmaceuticals and satellite telephones. My work with these clients has included extensive analysis of pricing, discounting and rebate data for disclosure to the government.

4) I have substantial experience in analyzing private insurance companies' claims data and reimbursement schedules. For example, I have worked with health insurance companies to analyze their claims and membership data to assess their Medicare coordination of benefits processes.

5) I have extensive experience assisting insurance and managed care companies with their reimbursement processes and practices, the related claims processing systems and output, contractual agreements, claims system assessments and validation procedures, and assessments of medical management practices.

6) I have experience working with Medicare Fiscal Intermediaries and Medicare Carriers to assist them with various government contracting requirements and the transitioning of Medicare claims processing activities to a successor contractor. I am therefore familiar with the operating structure of these organizations and their reimbursement processes.

7) I have experience assisting insurance and managed care companies in structuring and preparing proposals to perform managed care support contracts for the Department of Defense under the TRICARE program, which provides health insurance to active duty and retired military personnel and their families. My work has focused on assisting managed care companies structure and price operations to perform all requirements of the contract, including claims processing, customer service, provider relations, provider contracting, utilization management, and quality management. As part of these engagements, I have worked closely with the insurance companies' management as well as their actuarial and technical experts to make overall strategic pricing assessments relating to the various components of health care pricing and their related administrative costs.

8) I am being compensated at an hourly rate of $425.00. No portion of my firm's compensation is dependent on the nature of my findings or on the outcome of this matter. A list describing the data and information I relied upon is attached as Exhibit 2.

II. Scope of My Report

9) VEN-A-CARE OF THE FLORIDA KEYS, INC. ("VAC" or "Plaintiff") has brought suit against Abbott Laboratories Inc. ("Abbott") relating to the pricing and marketing of a certain drug, erythromycin, manufactured and sold by Abbott, and payments made by Medicaid programs to pharmacies for that drug. It is my understanding that VAC contends that Abbott caused the Medicaid programs to pay "excessive reimbursements" to pharmacies that dispensed the drug from 1994 through the first quarter of 2008.[1]

10) In support of the Plaintiff's claim that Abbott caused the Medicaid program to pay "excessive reimbursements" to pharmacies, the Plaintiff has served an expert report from Dr. Mark G. Duggan. Using a variety of data sets, and relying upon certain work conducted by two firms (Myers & Stauffer and Steck Consulting), Dr. Duggan has described his work as follows:

> This Report calculates a $15.559 million difference between (1) what the federal government reimbursed for certain pharmaceutical products dispensed to Medicaid recipients during the 1994Q1 to 2008Q1 period and (2) what the federal government would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC and Direct Price of Abbott products.[2]

11) I have been asked by counsel for Abbott to review, evaluate, and comment upon the analysis conducted by Dr. Duggan that led to his $15.559 million "DIFFERENCE" calculation.

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[1] See COMPLAINT for Violations of the False Claims Act, 3 U.S.C. Section 3729, et seq. Against ABBOTT LABORATORIES, INC. dated August 30, 2007 p. 2.

[2] See Dr. Duggan's Report dated March 27, 2009, p. 2.

12) Additionally, given my experience in the health care field, I have been asked to comment upon certain other assertions made in the Complaint.

III. Summary of Opinions

13) My primary concerns with Dr. Duggan's approach and his conclusions fall within the following categories:

- Dr. Duggan created his "Calculated Price"[3] by limiting his analysis to less than 27% of sales, selecting only negotiated contract sales to certain pharmacy customers.[4]
- Dr. Duggan ignored the important relationship between ingredient cost and dispensing fees in arriving upon the total reimbursement to a Medicaid pharmacy.
- Dr. Duggan calculated his "DIFFERENCE" by limiting his analysis to a sub-population of Medicaid reimbursement data (limited in both time and scope). Dr. Duggan extrapolated this limited information to other sub-populations including other states and other time periods that he chose not to analyze, in spite of the variability over time and among these populations.
- Dr. Duggan made no effort to either determine whether the reported prices for the drug at issue actually impacted the amounts paid by Medicaid or to quantify the extent to which reported prices impacted the amounts paid.[5]

14) I disagree with Dr. Duggan both in concept (i.e., that his proposed approach is appropriate) and application. I will expand on my concerns below.

15) I have also been asked to provide additional opinions related to the allegations in this matter. These opinions are included in Section X. of this report and relate to:

- Available sources of drug pricing information

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[3] For convenience, I use the term Dr. Duggan's "Calculated Price."

[4] Related to Dr. Duggan's alternative AWP and Direct Price, I compared the direct and indirect sales for the customer categories he analyzed (A003, A007, and M070).

[5] See Duggan Report dated March, 27 2009 p. 27 footnote 19.

- Context for spread allegations
- Effect of alleged spread on Medicaid utilization for this drug
- Use of Federal Upper Limit (FUL) by Centers for Medicaid and Medicare Services (CMS)
- Use of MAC pricing by states

IV. Abbott Drug at Issue

16) The Abbott drug named in this complaint is erythromycin, which is a self-administered antibiotic.[6] This drug has been on the market for decades and has faced extensive competition. Abbott marketed and sold the drug through its Pharmaceutical Products Division (PPD). The drug was available to customers that negotiated a contract with Abbott ("Contract" purchases) as well as those end customers that did not negotiate a contract with Abbott ("Non-contract" purchases). Abbott's primary customers included pharmacies, wholesalers, distributors, hospitals, and government purchasers.

A. How Abbott Sold the Drug

17) Customers purchased this drug directly from Abbott or through a wholesaler or distributor. When customers purchased directly from Abbott, Abbott distributed the drug to the customer. Some customers negotiated a contract with Abbott but arranged to take delivery of the drug through a wholesaler. This distribution system allowed customers ordering drugs from different manufacturers to streamline inventory and delivery. For contracted purchases, the wholesaler honored the contract

[6] "The company developed the antibiotic erythromycin, which, introduced under the brand names Erythromycin and E.E.S in 1952, constituted a significant portion of Abbott's prescription drug sales for several decades—even after the expiration of the 17-year patent." http://www.fundinguniverse.com/company-histories/Abbott-Laboratories-Company-History.html

price with the Abbott customer. The wholesaler then sought from Abbott any difference between the customer contract price and the original purchase price paid by the wholesaler.[7]

18) Customers without a negotiated contract with Abbott purchased the drug directly from Abbott or indirectly through a wholesaler or a distributor. Situations in which a customer might have purchased a drug without negotiating a contract included small customers that purchased in low volumes or customers that had contracts with other manufacturers of erythromycin but experienced supply problems. Wholesalers and distributors made "Non-contract" sales of this drug at market prices. Abbott had no visibility to the price paid by these customers.

V. Medicaid Payments

19) When a pharmacy provides this drug to a patient, the pharmacy receives a payment which includes a payment for the cost of the drug and the related dispensing fee. Some patients have private insurance or are covered by certain government programs like Medicare and Medicaid.[8] This case involves payments by Medicaid to pharmacies. The Medicaid program provides health care benefits to certain low-income individuals and families fitting into certain eligible groups defined by federal and state law. At the Federal level, the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration ("HCFA")), which is part of the United States Department of Health and Human Services ("HHS") provides oversight for the Medicaid programs.

[7] This amount is referred to as a "chargeback."

[8] It should be noted that this product was not reimbursed by Medicare until 2005.

20) CMS also administers the Medicaid Drug Rebate Program which requires a drug manufacturer to enter into a national rebate agreement with the Department of Health and Human Services (HHS) for states to receive Federal funding for outpatient drugs dispensed to Medicaid patients.[9] The Drug Rebate Program was designed to allow the state Medicaid programs to decrease drug expenditures by requiring manufacturers to pay a rebate to each state based on the state's utilization of the manufacturer's drugs.[10]

A. Medicaid Compensation to Pharmacies

21) The federal government outlines general guidelines for the program, and each state establishes, with approval of CMS, the requirements for its own program. During the period at issue, each Medicaid program provided payment to pharmacies under a prescription drug benefit. State Medicaid programs utilize various methods to compensate pharmacies for dispensing drugs, for example:

- Usual and customary charge (U&C)
- Actual acquisition cost plus dispensing fee
- Estimated acquisition cost (e.g. AWP – 15%; WAC + 9%) plus dispensing fee
- Federal upper limit (FUL) plus dispensing fee
- State maximum allowable cost (SMAC) plus dispensing fee

22) As explained by Myers & Stauffer in its reports to different state agencies, dispensing costs consist of both overhead and labor. Overhead includes prescription related costs (e.g. department fees, delivery expense, computer expense, containers

[9] See Schondelmeyer report dated June 20, 2008, p. 16.

[10] See Schondelmeyer report dated June 20, 2008, p. 56.

and labels) and costs related to both prescription and nonprescription sales (e.g. depreciation, real estate taxes, rent repairs, and utilities). Labor includes the total salaries, payroll taxes, and benefits paid to employees based on the time spent in the prescription department.[11]

B. Interrelationship of Ingredient and Dispensing Costs

23) The Federal and state governments as well as other experts in the field have long recognized the interrelationship between ingredient costs and dispensing fees in arriving at the Medicaid Programs' payment.[12] For example:

- A 1984 report to the Health Care Financing Administration, by the Office of the Inspector General, stated: "Any reduction in EAC screens by HCFA may well result in pressure by the pharmaceutical industry to increase state dispensing fees accordingly, and the net result may be zero."[13]
- A 1994 report to the Michigan legislature, by the Michigan Department of Social Services, stated: "EAC focuses on establishing screens at the lowest price that will maintain pharmacy participation regardless of the cost of the drug dispensed. The process of setting EAC screens is closely linked and balanced with setting dispensing fess. Payors are able to have low dispensing fee rates if they have high EAC screens. Particular attention must be given to setting EAC screens, since drug product costs are 84% of the pharmacy expenditures with only 16% for dispensing fees."[14]
- At a 1994 Health and Human Services meeting "to discuss and plan our nationwide review of the difference between the invoice price for drugs and AWP, for Medicaid pharmacy provider", state Medicaid officials "...expressed concern that our review was limited to one aspect of pharmacy reimbursement.

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[11] See "A Survey of Dispensing Costs of Pharmaceuticals in the Commonwealth of Kentucky, Prepared for the Kentucky Department of Medicaid Services, Prepared by Myers and Stauffer, December 2000, p. 8 – 14.

[12] See "Study of Medi-Cal Pharmacy Reimbursement" Prepared for the California Department of Health Services, prepared by Myers and Stauffer, June 2002, p. 12.

[13] Office of the Inspector General, Change to the Medicaid Prescription Drug Program Could Save Millions, 1984 p. 25.

[14] See MSA 33.

They said that any effort to lower the reimbursement for acquisition cost should also include some review of dispensing fees."[15]

- At a 1995 Health and Human services meeting to discuss the findings, "state officials believed that the report should include the following disclaimer to avoid uniformed State officials who might overreact to the report without considering other aspects of reimbursement":

> Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, physician consultations; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead. We also did not take into consideration the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations.[16]

- Jerry Dubberly of the Georgia Department of Community Health stated: "We underpaid on the dispensing fee because we overpaid on the ingredient" and that this practice was employed by other state Medicaid programs.[17]

- A variety of reports prepared by Myers and Stauffer at the request of state officials:

  - A 1998 report to the state of Kentucky stated: "The professional fee and ingredient cost components of the pharmacy reimbursement formula should be assessed in conjunction."[18]

  - A 1999 report to the state of Kansas stated: "Although not a component of the dispensing cost survey undertaken by Myers and

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[15] See HHD022-0201 – HHD022-0203

[16] See HHD021-0121 - HHD021-0122

[17] See Dubberly Dep. December 15, 2008 p. 331; See also Sullivan Dep. March 12, 2008 p. 328 – 329; See also Gorospe Dep. March 19, 2008 p. 279 – 282; See also McCann Dep. October 3, 2007 p. 216 – 217; See also Wiberg Dep. March 14, 2008, p. 185.

[18] See "A Survey of Costs of Dispensing Prescriptions and Estimated Acquisition Cost in the State of Kentucky" Prepared for the Commonwealth of Kentucky Division of Administration and Development Cabinet for Health Services, Prepared by Myers and Stauffer, Prepared by Myers and Stauffer, August 1998 p. 2.

Stauffer, a discussion of costs incurred by pharmacies is not complete without mention of ingredient acquisition cost."[19]

- A 2002 report to the state of California stated: "These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement."[20]

- A 2007 report to the state of Nevada stated: "Cost of providing services is also a consideration for the evaluation of the adequacy of Medicaid pharmacy dispensing and ingredient reimbursement rates. A comparison of current pharmacy reimbursement rates with provider cost should consider findings related to dispensing cost in conjunction with ingredient reimbursement. The Department's current pharmacy dispensing fee is lower than the average cost of dispensing prescriptions. However, on the average, Myers and Stauffer estimates that pharmacies realize positive net margins on Medicaid prescriptions due to margins on drug ingredient cost."[21]

- A 2007 report to the state of California stated: "This finding alone does not indicate that the current dispensing fee is inadequate since dispensing fees should be considered in conjunction with ingredient reimbursement rates."[22]

- A 2005 report to State Medicaid Directors, by the Department of Health and Human Services, stated: "When using these new drug data sources, States should reexamine and reevaluate the reasonableness of the dispensing fee paid as part of the pharmacy claim. If States adjust their payment methodologies to

[19] See "A Survey of Dispensing Costs of Pharmaceuticals in the State of Kansas" Prepared for the Kansas Department of Social and Rehabilitation Services, Prepared by Myers and Stauffer, September 1999 p. 36.

[20] See "A Survey of Acquisition Costs of Pharmaceuticals in the State of California" Prepared for the California Department of Health Services, Prepared by Myers and Stauffer June 2002 p. 5.

[21] See "Survey of Dispensing Costs of Pharmaceuticals in the State of Nevada" Prepared for the Nevada Department of Human Resources Division of Health Care Financing and Policy, Prepared by Myers and Stauffer December 2007 p.6

[22] See "Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of California, Prepared for the California Department of Health Services, Prepared by Myers and Stauffer, December 2007 p. 9.

reflect the ingredient cost of the prescription drug, we suggest they also reevaluate their dispensing fees to ensure that these fees are reasonable."[23]

- A 2006 report to the Maryland legislature, by the Maryland Department of Health and Mental Hygiene, stated: "The dispensing fee that is assessed by the pharmacy itself is a fixed amount. *Both components – estimated acquisition costs and actual dispensing fees – must be considered when determining whether pharmacists are paid appropriately.*"[24]

- At a 2008 deposition, North Carolina Pharmacy Director, Benny Ridout, testified: "It was always the feeling, I think, of the pharmacy directors, those states that had a fee that was lower than what it cost to fill a prescription, that if they took anything off one side, they would have to put some on the other side to help so the pharmacists could make it. So if you got the actual acquisition cost on one side, and your fee didn't cover his cost to fill the prescription, you would have to raise that fee. In fact, I made that known to the OIG itself."[25]

- A 2008 letter to the Texas Health and Human Services Commission (HHSC), from the President of the Texas Pharmacy Association, President of the Federation of Drug Stores, and the Regional Director of State Government Affairs for the National Association of Drug Stores, stated: "The 2008-09 HHSC budget also included a rider directing the agency to raise up to $12.50 the dispensing fee for generic drugs, if the proposed federal AMP standards were implemented that are expected to reduce pharmacy reimbursement below actual drug cost."[26]

- A 2009 report to the California Pharmacists Association, by Professor Schondelmeyer, stated: "If the payment method sets the prescription payment amount below the actual costs for either drug product cost, cost of dispensing and related additional costs, or both, then problems with Medicare (sic) [Medicaid] beneficiary access to pharmacy services will occur."[27]

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[23] See "Implementation of the Deficit Reduction Act of 2005 (DRA)" Release No. 144, Prepared by Centers for Medicare and Medicaid Services Release for State Medicaid Directors, December 15, 2006.

[24] See MD0003816.

[25] See Ridout Dep. December 5, 2008 p. 142.

[26] See Letter to Chairwoman Choi of the HHSC Council Subcommittee on the LAR dated August 8, 2008.

[27] See "Impact of the 5 Percent Fee-for-Service Payment Reductions on Medi-Cal Beneficiaries and Pharmacies" Prepared for the California Pharmacists Association, Prepared by Stephen Schondelmeyer, February 11, 2009 p.ii.

C. Medicaid Dispensing Fees Have Been Widely Recognized as Inadequate

24) For years, dispensing cost studies have shown the actual cost of dispensing drugs by pharmacies to be much greater than the dispensing fees paid by Medicaid. Myers & Stauffer performed numerous analyses for many Medicaid agencies on pharmacy dispensing costs. These analyses included data collected on over 100 pharmacy surveys.

25) With respect to the cost of dispensing these drugs, the following information has been submitted to state officials by various experts, for example:

- A 1998 report to the Kentucky Department of Medicaid Services, by Myers and Stauffer, stated: "This study has determined that the weighted median cost of Medicaid dispensing, excluding IV providers, is $4.37 ($4.62 including the tax), and further that many presumed economical and efficient pharmacies are able to fill a prescription for $3.83 or less (plus $0.25 tax). The results of the acquisition cost study indicate that at the State's current reimbursement formula allows pharmacy providers an excess cost of goods reimbursement of $3.30 on the typical Medicaid prescription, which can conceptually be applied as an offset to dispensing cost."[28]
- A 2002 report to the California Department of Health Services, by Myers and Stauffer, stated: "The Department's current pharmacy dispensing fee is below the average cost of dispensing prescriptions. This finding alone does not indicate that the current pharmacy reimbursement rates are inadequate since both dispensing and ingredient reimbursement should be considered in tandem. Should the Department desire to more closely match the pharmacy dispensing fee with observed pharmacy dispensing cost, then an increase in the dispensing fee would be appropriate. Such an increase would be most appropriately considered in conjunction with an adjustment the Department may make in pharmaceutical ingredient reimbursement."[29]

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[28] See "A Survey of Costs of Dispensing Prescriptions and Estimated Acquisition Cost in the State of Kentucky" Prepared for the Commonwealth of Kentucky Division of Administration and Development Cabinet for Health Services, prepared by Myers and Stauffer, Prepared by Myers and Stauffer, August 1998 p. 8.

[29] See "Study of Medi-Cal Pharmacy Reimbursement" Prepared for the California Department of Health Services, Prepared by Myers and Stauffer, June 2002 p. 6.

- A 2006 report to the Maryland legislature, by the Maryland Department of Health and Mental Hygiene, stated: "The provision in the Deficit Reduction Act applies only to a drug's ingredient costs and does not include dispensing fees, which continue to be determined by that states. Maryland's Medicaid dispensing fees - $2.69 for nonpreferred brand-name drugs and $3.69 for preferred brands and generics – fall well below the national average of $4.50. The low dispensing fee, combined with the reductions in reimbursement for ingredient costs, could reduce Medicaid payments for prescription drugs below what it costs pharmacy to purchase and dispense the drugs."[30]

- A 2006 report to the Maryland legislature, by the University of Maryland School of Pharmacy: Pharmaceutical Health Services Research Department, stated: "In summary, the cost of dispensing a prescription in Maryland varies based upon a number of factors and range from more than $7 to as much as $12, depending on ownership type, volume of prescriptions, and the percentage of prescriptions paid for by Medicaid. The reported costs from the 1990s and are consistent with other figures that have been reported in the last few years for other states."[31]

- A 2009 report to the California Pharmacists Association, by Professor Schondelmeyer, stated: "Given the substantial reduction in payment for prescriptions mandated by the California statute, many pharmacies will receive payment that falls considerably short of their actual breakeven costs (i.e., both drug ingredient costs and costs of dispensing). Any reasonable pharmacy (i.e., business manager or owner) would be unwilling to provide prescriptions when the total payment falls short of the total actual drug product costs and the costs of dispensing and other related costs."[32]

- A 2007 study by Grant Thornton stated the following which is summarized in Figure 1[33]:

[30] See MD0003814.

[31] See MD0003825.

[32] See "Impact of the 5 Percent Fee-for-Service Payment Reductions on Medi-Cal Beneficiaries and Pharmacies" Prepared for the California Pharmacists Association, Prepared by Stephen Schondelmeyer, February 11, 2009 p. ii.

[33] See "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies" Prepared for: The Coalition for Community Pharmacy Action (CCPA), Prepared by Grant Thornton LLP, January 2007 p. 16.

Figure 1

Grant Thornton: Medicaid Cost of Dispensing					
Description	Frequency	Mean	Median	25th Percentile	75th Percentile
Medicaid COD per Prescription[1]	65,037,250	$10.51	$9.87	$8.52	$11.62
Medicaid COD per Pharmacy[2]	22,123[3]	$12.81	$11.22	$9.36	$14.06

[1] Weighted data by volume of Medicaid prescriptions for which Medicaid COD could be computed; each Medicaid COD as one value.

[2] Unweighted data; each pharmacy's Medicaid COD as one value, regardless of its Medicaid prescription volume.

[3] 1,029 pharmacies reported no medicaid prescription volume and/or did not provide sufficient information to compute a Medicaid COD.

VI. Dr. Duggan's "DIFFERENCE" Methodology

26) Dr. Duggan calculated his "DIFFERENCE" by comparing the amount he contends was paid to pharmacies and an amount that he believed would have been paid utilizing his "Calculated Prices". With these "Calculated Prices" Dr. Duggan created his alternative prices including his alternative AWP, WAC, and Direct Price that he then used to arrive at his "but for" reimbursement for Medicaid.[34]

Duggan's Reimbursement Paid – Duggan's "but for" Reimbursement = Difference

VII. Dr. Duggan's Analysis of "but for" Reimbursement for This Drug

27) Dr. Duggan created three different "Calculated Prices", representing AWP, WAC, and Direct Price, which he inserts into each state's payment formula.[35] This "Calculated Price" is then used as part of his formula to generate a "but for" drug cost component. Contrary to the facts shown in section V. D. above, Dr. Duggan does not modify the dispensing fee component of his drug reimbursement amount and does not

[34] See Dr. Duggan's report March 27, 2009 p.9. Dr. Duggan calculated his alternative published prices for AWP and Direct Price by adding 25% to his "Calculated Price".

[35] See Dr. Duggan March 27, 2009 p. 7.

consider its impact on what actually would have been paid to the pharmacy. His partially modified "but for" reimbursement amount is then compared to the amount he contends was actually paid by Medicaid to the pharmacy to arrive at his "DIFFERENCE" calculation.

A. Dr. Duggan's Alternative AWP

28) In calculating his alternative AWP, Dr. Duggan limited his analysis to indirect transactions for three retail pharmacy classes of trade. He then calculated a weighted average of these transactions and scaled it by 125%.[36] Dr. Duggan substituted his alternative AWP into the state payment formula. Dr. Duggan applied this alternative AWP to 54% of the state claims data.[37]

29) By focusing on only indirect retail pharmacy transactions, Dr. Duggan failed to consider prices paid by other pharmacy customers who purchased directly from Abbott at a different price or directly from a wholesaler or distributor at a "Non-contract" price unknown by Abbott.

30) Dr. Duggan admits that a full 20% of the packages purchased from wholesalers do not appear in Abbott's indirect sales data.[38] Abbott does not have visibility into these sales because the transactions are to "Non-contract" customers who purchased through a wholesaler. Dr. Duggan attempted to account for these sales through his 125% scaling factor. Dr. Duggan testified:

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[36] See Dr. Duggan report dated March 27, 2009 p. 9.

[37] Calculated where an alternative price was applied to state claims data as determined by a review of Dr. Duggan's STATA logic.

[38] See Dr. Duggan report dated March 27, 2009 p. 19.

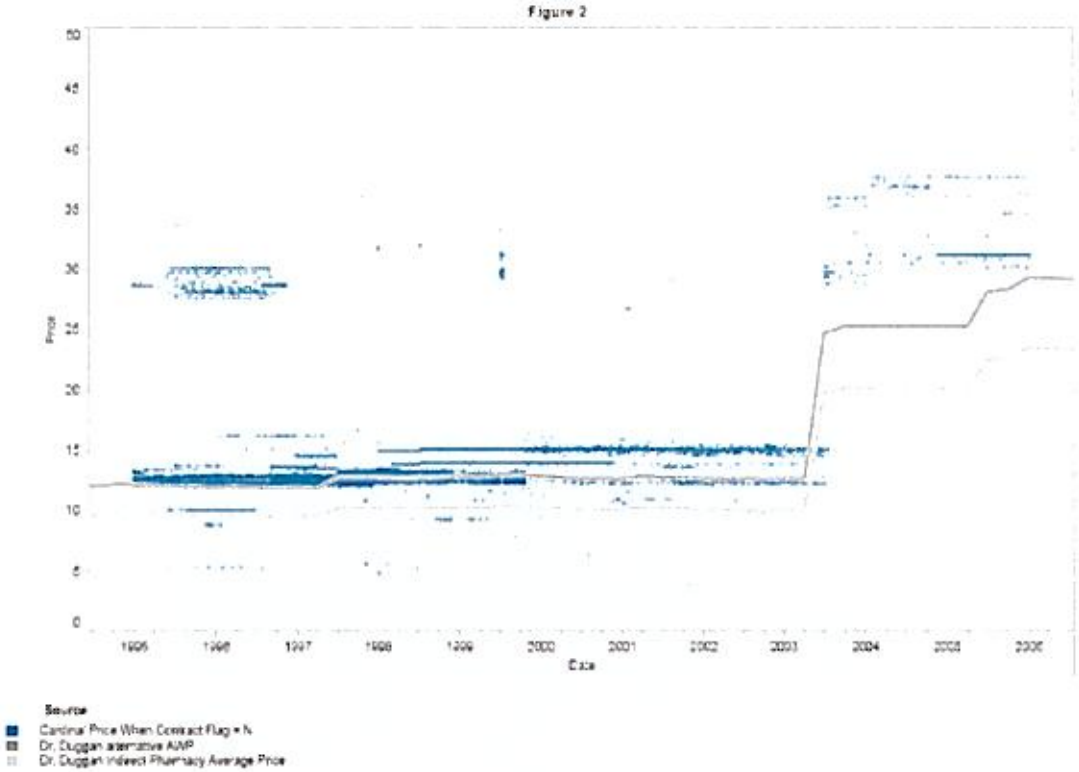
> I explore the relationship between the prices in Abbott's indirect data and those in the Cardinal data, which would include off-contract sales just to get a sense of whether there is significant variation between my alterative AWPs and the average prices in the wholesaler data. And I find, as mentioned earlier, that if anything my prices once scaled tend to much more often than not exceed the average price in the wholesaler data.[39]

31) This analysis of the Cardinal average price does not accomplish Dr. Duggan's objective: to determine whether the "Non-contracted" sales are higher than his scaled alternative AWP. Dr. Duggan acknowledges that 37.4% of the time his alternative AWP is lower than the Cardinal average price.[40]

32) I analyzed the Cardinal average "Non-contracted" transaction prices and Dr. Duggan's alternative AWP to demonstrate that Dr. Duggan failed to adequately address "Non-contracted" sales. Figure 2 highlights that Ery-Tab 333mg (NDC 00074632013) "Non-contract" Cardinal transaction prices tend to be above both Dr. Duggan's "Calculated Price" and his alternative AWP. This comparison highlights the fact that Dr. Duggan's "Calculated Price" does not account for acquisition costs paid by a significant portion of the retail marketplace. This problem is magnified by the fact that most states pay less than AWP (i.e., AWP – 15%), which results in even lower reimbursements to these "Non-contracted" pharmacies.

[39] See Duggan Dep. April 17, 2009 p. 47.

[40] See Duggan Report p. 20.



33) Nearly $60 million of wholesaler and distributor sales to "Non-contract" end purchasers were not considered in Dr. Duggan's analysis.[41] Dr. Duggan's approach would therefore result in many pharmacies, such as those without negotiated contracts with Abbott, who purchased from a wholesaler or distributor, being reimbursed below the price they paid for the drug. States' reimbursement policies for ingredient costs were aimed to cover the acquisition cost of pharmacies participating in their Medicaid Program thereby allowing adequate access to care for Medicaid beneficiaries throughout the State.[42]

[41] I calculated the total direct sales for wholesalers (W050, M060, M061, P040) less indirect sales and chargebacks to determine the undiscounted sales.

[42] See Wells Dep. December 15, 2008 p. 231 – 233; See Robinson Dep. February 7, 2008, p. 333 – 334.

B. Dr. Duggan's Alternative WAC

34) For purposes of calculating his "DIFFERENCE", Dr. Duggan utilized another methodology for determining his alternative WAC. Dr. Duggan relies upon an average for his calculation. The result of his approach implies that roughly one half of the purchases will be at prices above his alternative WAC. Dr. Duggan's alternative WAC price is applied to 10% of the state claims data.[43]

35) Dr. Duggan analyzed purchases between Abbott and one wholesaler class of trade. He included the chargeback amounts for all contracted customers when calculating the alternative WAC. This would include sales outside Dr. Duggan's pharmacy classes of trade such as sales to government and hospitals, which are not reimbursed by the Medicaid pharmacy benefit at issue in this matter. Figure 3 demonstrates that government and hospitals, which represent approximately 29% of packages at issue. Including sales to these types of customers inappropriately lowers Dr. Duggan's alternative WAC.

Figure 3

1994 - 2007					
Customer	**Total Packages**	**Sales**		**Average Price per Package**	
Government	2,536,125	$	21,902,562	$	8.64
Hospital	1,372,972	$	12,421,070	$	9.05
Other	674,406	$	7,067,593	$	10.48
Pharmacy	9,555,791	$	129,658,626	$	13.57
"Non-Contract" Retail Sales	4,127,255	$	60,311,746	$	14.61

[43] Calculated where an alternative price was applied to state claims data as determined by a review of Dr. Duggan's STATA logic.

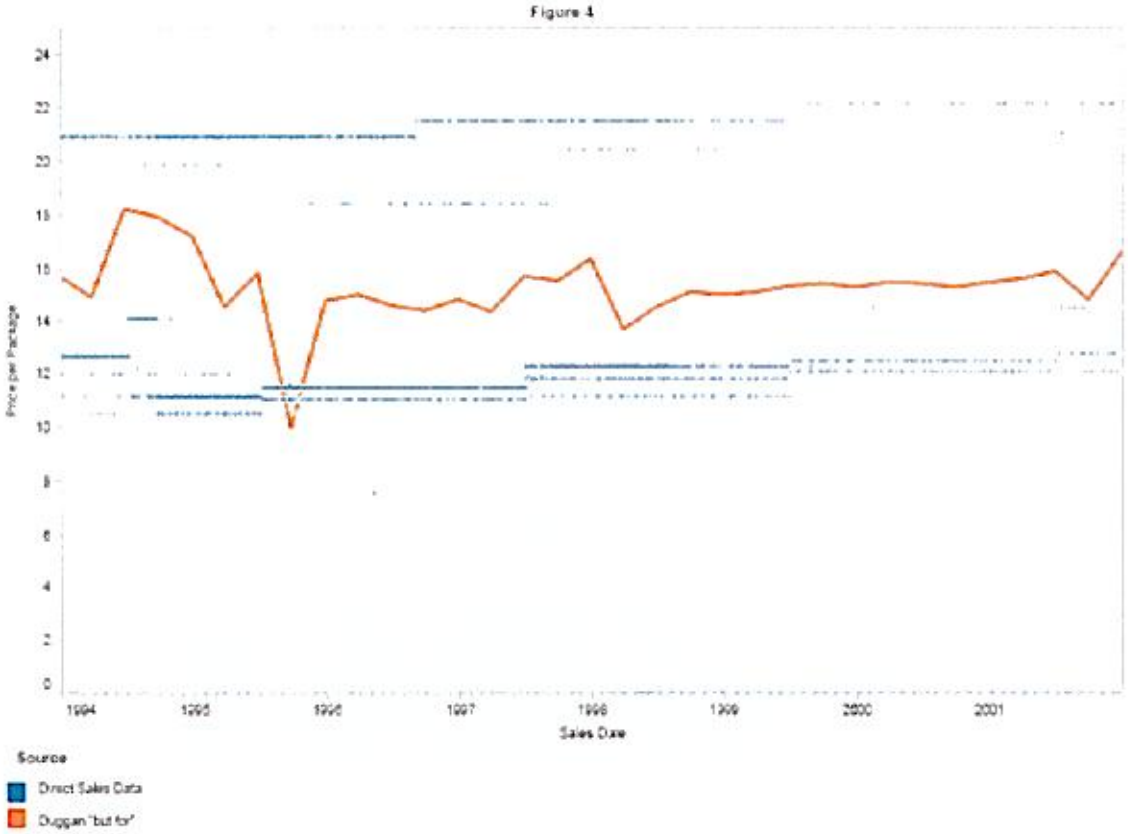
C. Dr. Duggan's Alternative Direct Price

36) Dr. Duggan created an alternative Direct Price by averaging sales to certain pharmacy classes of trade who purchased directly from Abbott. This creates issues in his "but for" amounts as described below. Dr. Duggan's alternative direct price is applied to 34% of the state claims data.[44]

37) Figure 4 outlines direct sales per package for Dr. Duggan's 3 classes of trade related to Erythromycin Stearate 500mg Tab 100's (NDC 00074631613) for the period when Dr. Duggan uses the alternative direct price to arrive at a "DIFFERENCE". The graph highlights the multiple price points in the marketplace at a given time period; the variability between quarters of Dr. Duggan's alternative direct price; and the 25% of direct sales that take place above Dr. Duggan's alternative direct price.[45]

[44] Calculated where an alternative price was applied to state claims data as determined by a review of Dr. Duggan's STATA logic.

[45] Calculated the number of transactions occurring above Dr. Duggan's "but for" for NDC00074631613.



38) Some of the variability in Dr. Duggan's "but for" prices is caused by Dr. Duggan's failure to properly account for credit transactions in the sales data. When the sales transactions are properly matched, Dr. Duggan's "but for" price would be higher and thus result in a lower alleged "DIFFERENCE."[46] Dr. Duggan made no attempt to investigate this or other issues within the data, as he explained, "I did not drill down on that specific thing...I'm sure there's an explanation for it."[47] Furthermore, the

[46] As seen in Figure 4, the significantly lower "but for" price in 1995 Q4 is caused by a credit attributed to a transaction in 1995 Q1. The significant decrease in Dr. Duggan's "but for" causes a increase in damages for that period.

[47] See Duggan Dep. April 17, 2009 p. 64.

numerous transactions occurring above Dr. Duggan's "but for" direct prices would result in payments to numerous pharmacies below their acquisition cost.

VIII. Dr. Duggan's Analysis of Reimbursement Paid for This Drug

39) Dr. Duggan attempted to quantify the actual payment by Medicaid by analyzing claims information for a limited number of states for limited time periods, and he extrapolated the results to other states and periods for which he chose and/or did not have data to analyze.[48]

A. Dr. Duggan Limited His Review of Actual Claims Data

40) Rather than analyzing actual claims data from every state at issue over the entire time period, Dr. Duggan chose to calculate his Medicaid "DIFFERENCE" by extrapolating from a limited number of states for a limited period of time. Dr. Duggan limited his analysis of actual detailed claims data for up to 15 states.

- In no state did he look at actual claims data over the entire time period (e.g., Dr. Duggan only analyzes 6 years of actual claims data out of the 14 year time period for Virginia).
- Within the 15 states where Dr. Duggan chose to analyze some actual detailed claims data, he simply extrapolated the results from the earliest available quarter to all other quarters where he did not look at actual claims data at all.[49] The actual detailed claims data reviewed by Dr. Duggan only represents 22% of the quarters for which he calculates a difference.[50]

41) Figure 5 identifies the limited actual Medicaid claims data reviewed by Dr. Duggan.

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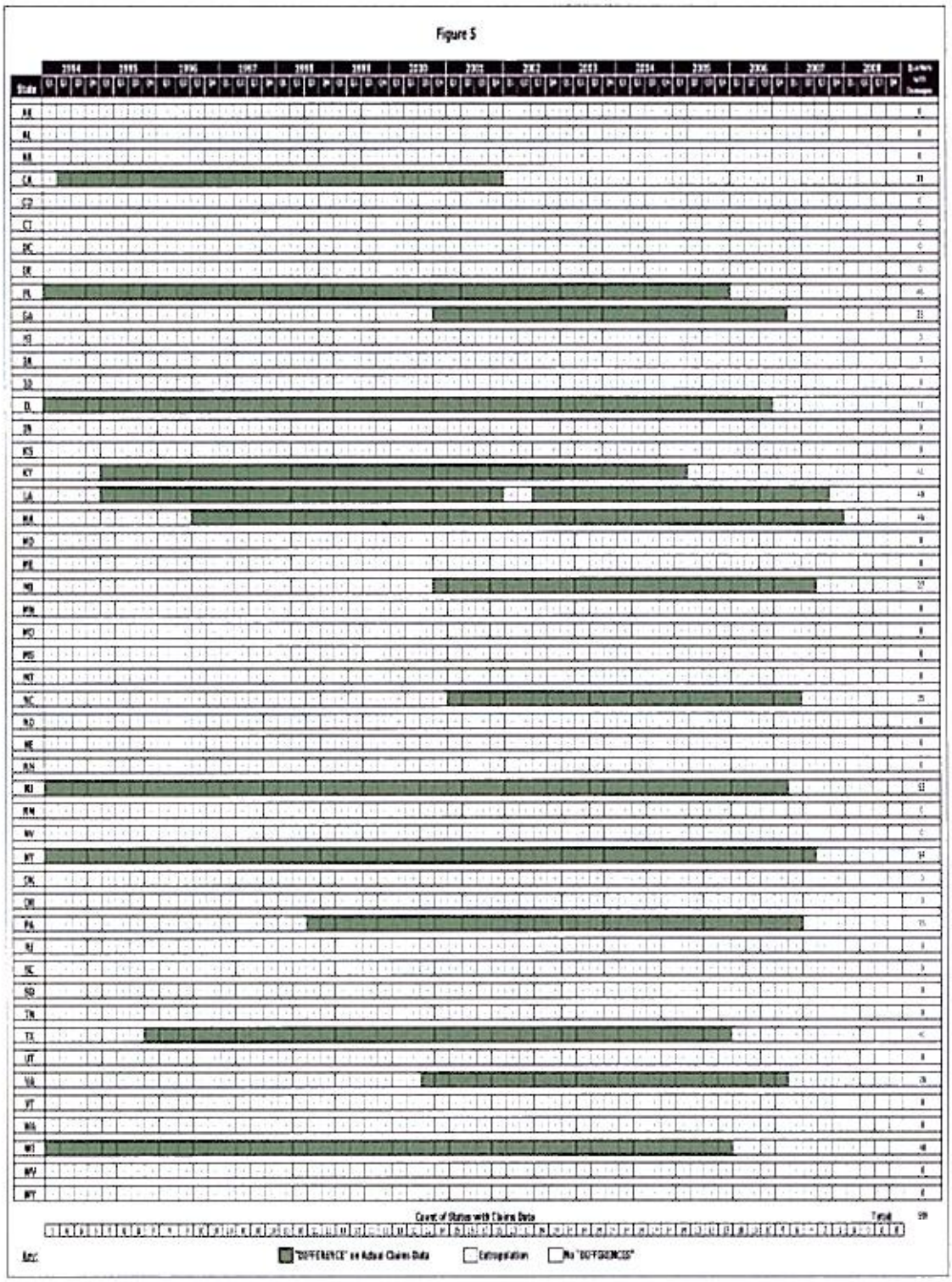
[48] Dr. Duggan has not calculated differences for Arizona or Ohio. See footnote 14 on p. 22 of Dr. Duggan's report dated March 27, 2009.

[49] Dr. Duggan also extrapolated the number of claims with a "DIFFERENCE" for periods that he did analyze using a random number generator function to determine those he counts as "DIFFERENCE" claims.

[50] I calculated the actual state claims data quarters divided by total claim quarters.

Figure 5



42) Dr. Duggan utilized several different research data sets for periods when he did not have actual claims data. The analyzed state claims data was the basis on which he extrapolated to the unanalyzed research data.

- The State Medicaid Research Files (SMRF) data, which is available up to 1998, contains individual claim level transactions for the purpose of producing data to support research and policy analysis on Medicaid populations.[51] The transaction level detail contains the provider charge and payment amounts, which is comprised of a combination of the ingredient cost and dispensing fee. The information does not contain drug unit information for a given claim. The SMRF data was replaced by the Medicaid Analytical eXtract (MAX), which is available from 1999 – current, and is also produced to support research and policy analysis.[52] The SMRF/MAX data is used as the basis for calculating 31% of claims with a "DIFFERENCE".[53]

- The State Drug Utilization Data (SDUD) contains summary level information for covered outpatient drugs paid for by State Medicaid agencies since 1990, the start of the Drug Rebate Program.[54] The data, summarized by NDC, year, and quarter, is aggregated and does not break out ingredient cost and dispensing fee. According to Dr. Duggan this data set does not allow the "opportunity to...look at it transaction by transaction or claim by claim."[55] The SDUD is used as the basis of calculating 14% of claims with a "DIFFERENCE".[56]

- The Medicaid Statistical Information System's (MSIS) purpose is to collect, manage, analyze, and disseminate information on eligible[s], beneficiaries, utilization and payment for services covered by State Medicaid programs.[57] Similar to these other data sets, MSIS data does not separately identify ingredient cost and dispensing fee. The MSIS

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[51] http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/01_Overview.asp.

[52] See http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/07_MAXGeneralInformation.asp.

[53] I calculated "# Clms w/DIFF>0" for a "Source" divided by the total "# Clms w/Diff>0".

[54] The drug rebate program was amended by the Veterans Health Care Act of 1992 (VHCA). Under VHCA, drug manufacturers are required to enter a pricing agreement with HHS for the section 340B Drug Pricing Program, which is administered by the Health Resources and Services Administration.

[55] See Dr. Duggan deposition dated April 17, 2009 p. 110.

[56] I calculated "# Clms w/DIFF>0" for a "Source" divided by the total "# Clms w/Diff>0".

[57] See http://www.cms.hhs.gov/MedicaidDataSourcesGenInfo/02_MSISData.asp.

data is used as the basis of calculating 2% of claims with a "DIFFERENCE."[58]

B. Dr. Duggan Extrapolated To Unanalyzed Populations

43) Dr. Duggan calculated a "DIFFERENCE" on claims data for 22% of the quarters which represents only roughly one half of the reimbursements at issue and extrapolated his results to the unanalyzed reimbursements for other periods and other states.[59] Dr. Duggan has not articulated a sufficient basis for assuming that the populations he extrapolated from are comparable to the populations he extrapolated to. Instead, he merely:

- Analyzed the Medicaid reimbursement methodologies and concluded that the 15 states are "quite similar" to the 34 states.[60]
- Attempted to compare the average cost per claim (1999 – 2004) for the 15 states he chose to analyze to the 34 states he chose not to analyze.[61]

44) Dr. Duggan explains that his sample represents 74% of the total Medicaid spending by state; however, he does not have actual claims data for all time periods for these states.[62] In reality, Dr. Duggan only analyzed claims data for approximately 51% of Medicaid spending at issue.[63]

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[58] I calculated "# Clms w/DIFF>0" for a "Source" divided by the total "# Clms w/Diff>0".

[59] I calculated actual state claims data quarters divided by total claim quarters and actual state claims reimbursements divided by total reimbursements.

[60] Duggan report March 27, 2009 p. 90.

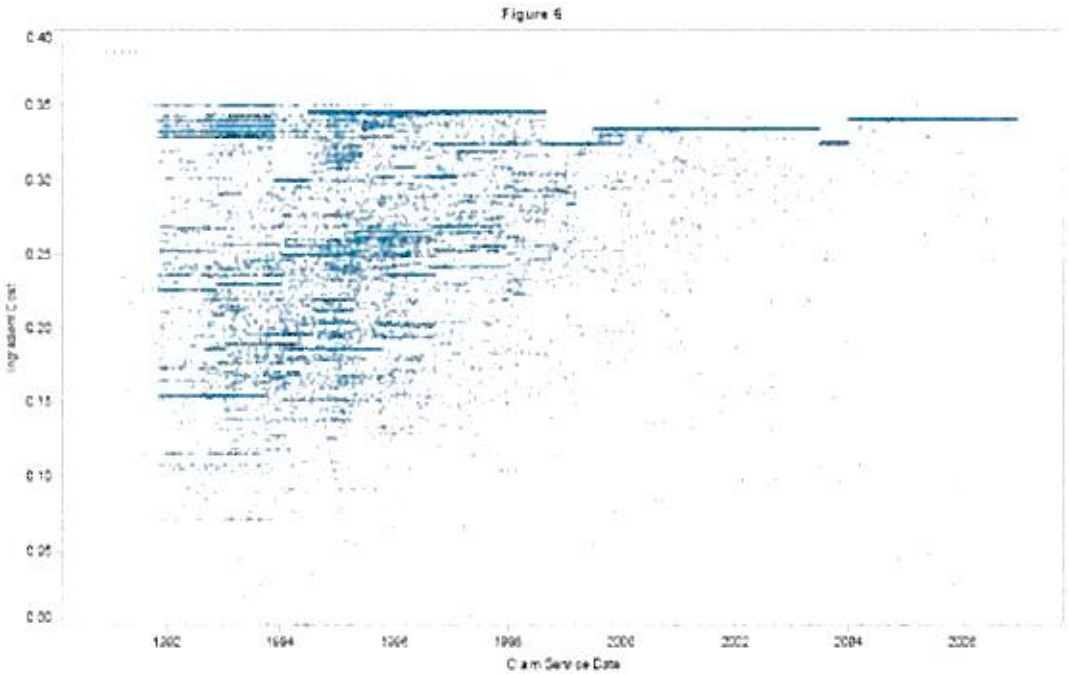
[61] Duggan report March 27, 2009 p. 90 - 91.

[62] Duggan report March 27, 2009 p. 88.

[63] Dr. Duggan's 74% statistic does not take into consideration periods where he uses other data sets (e.g. SDUD) for the 15 states. If those data sets had been considered, his statistic would fall to 51%.

1. Dr. Duggan's Methodology Did Not Consider the Variability of Medicaid Payments Across States

45) Dr. Duggan made no attempt to determine the basis of payment for the claims for which he seeks recovery in this case but rather assumes liability for all of the claims for which he calculated a "DIFFERENCE".[64] Figure 6 illustrates one of many examples of the variability in the per unit payments for erythromycin, more specifically Ery-Tab 333mg (NDC00074632013) in the state of New Jersey, for which Dr. Duggan calculates a "DIFFERENCE."



46) Dr. Duggan used actual claims data for the 15 states for limited periods. Dr. Duggan then extrapolated from those 15 states to aggregate spending data for the

[64] While Dr. Duggan did not calculate a difference on FUL transactions in the state of New York, Dr. Duggan does not identify or exclude such transactions in other states.

34 other states by NDC and by quarter. It is important to note that the aggregate spending data (i.e., SMRF and SDUD data – Include MSIS MAX) included dispensing fees. I have identified a number of problems arising from Dr. Duggan's extrapolation of actual Medicaid claims data to his unanalyzed populations. For example:

- Dr. Duggan did not consider the wide variation of ingredient reimbursement formulas across states.[65]
    - Dr. Duggan did not consider the various state MAC programs in his analysis. Throughout the period at least 20 states performed their own determination of a MAC price to be paid to pharmacies for erythromycin.[66] The prevalence of MAC pricing increased over time.
    - Dr. Duggan did not consider individual states' definitions of Usual and Customary (U&C) (e.g., Arkansas, Rhode Island, and Vermont).[67]
- Dr. Duggan ignored individual states' intentions to provide a margin to pharmacies related to the reimbursement for this drug.[68]
- Dr. Duggan did not consider the "mark-up" included in the calculation of the FUL.

2. Dr. Duggan's Methodology Did Not Consider the Variability of Dispensing Fees

47) Dr. Duggan's extrapolations do not consider the differences across states in both amount and treatment of dispensing fees for this drug. Dispensing fees for

[65] See HHD006-0060.

[66] See various State MAC lists, Exhibit 2.

[67] See HHD127-0023 – HHD127-0025 (For example, the state of Massachusetts defines Usual and Customary as "the lowest price for a given volume of drugs that a pharmacy charges to or accepts as payment from any purchaser or reimburser, including those with contracts that represent less than one percent of the pharmacy's total prescriptions revenue").

[68] See Dubberly Dep. December 15, 2008, p. 331; See Terrebonne Dep. March 31, 2008, p. 162 and p. 216 - 217; See Dep. Parker November 18, 2008, p. 267 – 268; See Robinson Dep. February 7, 2008, p. 320 – 321.

erythromycin range from 2.50 to 5.77.[69] Based on Dr. Duggan's small "DIFFERENCE" per prescription for erythromycin, this variability in dispensing fees can represent a significant portion of the Medicaid drug expenditure.

C. Dr. Duggan Ignored the Established Interrelationship of Ingredient Cost and Dispensing Fees

48) The reimbursement paid to pharmacies for this drug is comprised of both ingredient cost and dispensing fees. As described previously, it is well established that payors and pharmacies view both components together when assessing the adequacy of the reimbursement.

49) Dr. Duggan ignored the important interrelationship between these components of reimbursement and he did not properly adjust dispensing fees when he lowered his drug reimbursement levels. The need for this adjustment has been recognized by State Medicaid Agencies and the consultants that advised them.

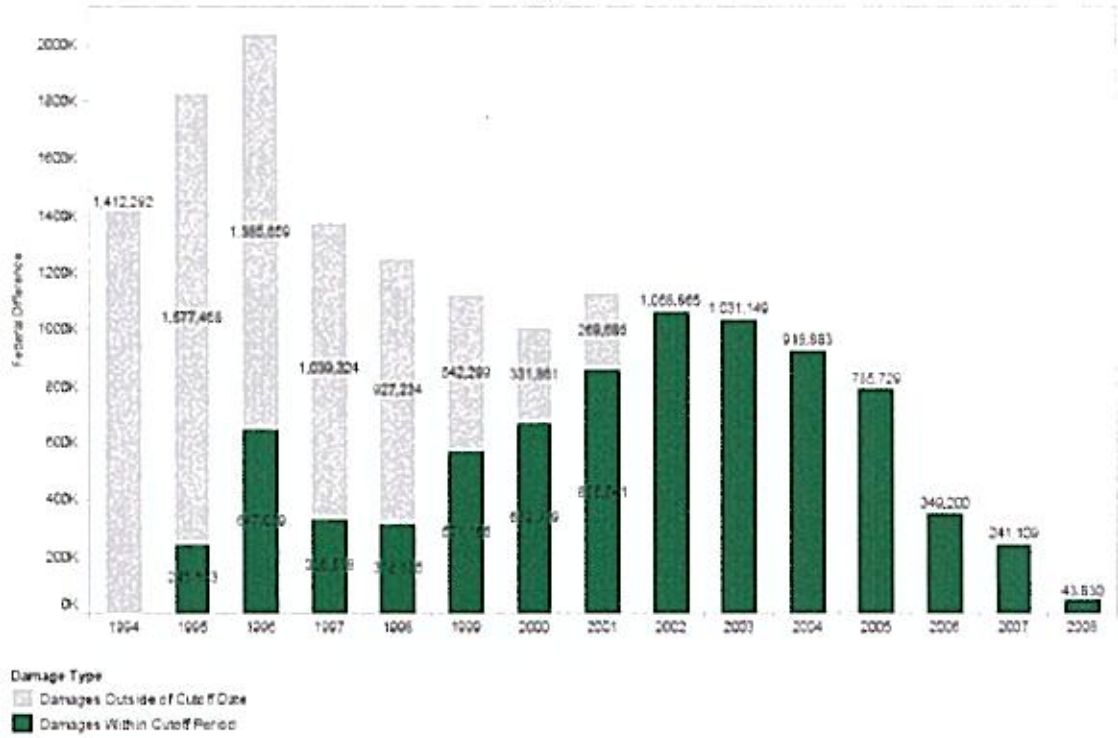
IX. Dr. Duggan's "DIFFERENCEs" Are Also Impacted By Various Other Factors

A. Analysis of Dr. Duggan's "DIFFERENCE" Period

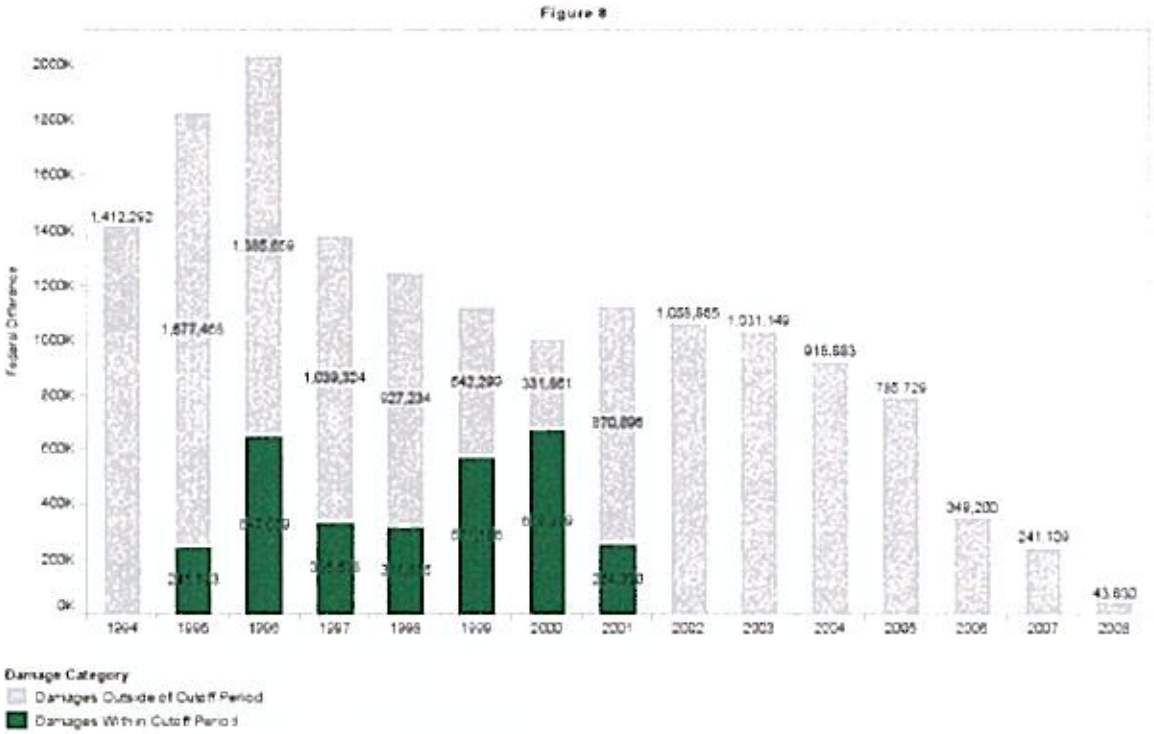
50) I have been asked by counsel to quantify the percentage of "DIFFERENCE" attributable to the time period associated with the various statute of limitations related to each NDC. Figure 7 shows the impact of the statue of limitations on the NDCs.

[69] See Myers and Stauffer State Summaries for Tennessee and Louisiana.

Figure 7



51) I have also been asked by counsel to quantify the percentage of "DIFFERENCE" attributable to the time period associated with the various statute of limitations related to each NDC and applying the complaint filing date February 15, 2001. Figure 8 illustrates the application of these dates.



B. Dr. Duggan's "DIFFERENCE" Includes Claims That Have Been Resolved

52) Dr. Duggan calculated the "DIFFERENCE" for the Federal share of Medicaid for all states.[70] I have been advised that certain settlements have been reached that resolve Medicaid claims for the drug at issue. I will be prepared at trial to quantify any offsets that should be made to the government's proposed "DIFFERENCE" on this basis.

53) In addition, various Medicaid pharmacies have returned funds to the government related to incorrect or inappropriate claims during this eleven year period. Dr. Duggan has not considered the impact of this recoupment.

[70] See Dr. Duggan's report dated March 27, 2009 p. 9.

C. Dr. Duggan's "DIFFERENCE" Does Not Account for the Rebates Paid by Abbott to Every State Medicaid Program

54) Dr. Duggan ignored Medicaid rebates in his calculations of "DIFFERENCE." As discussed earlier, Abbott made quarterly submissions to CMS of its AMP and issued rebate checks to each state Medicaid program resulting in a net reduction in the Medicaid expenditures for Abbott's drug. For purposes of his calculations, he has not offset his "DIFFERENCE" by the Medicaid rebates paid by Abbott for the drug for the relevant time period.

X. Other Opinions

55) I have also been asked my opinion with the respect to the following issues:

A. Available Sources of Drug Pricing Information

56) During the relevant time period, there was a variety of pricing information available to the government. For example:

- Myers & Stauffer conducted various pharmacy purchase price and dispensing cost surveys on behalf of state Medicaid agencies during the relevant time period. Some of these states in fact overlapped the states analyzed by Dr. Duggan including California, Kentucky, Florida, New Jersey, and Louisiana. In addition, Myers & Stauffer performed similar projects for many of the states Dr. Duggan chose not to analyze.[71]
- On a quarterly basis, Abbott provided CMS with its Average Manufacturer Prices (AMP). AMP is calculated based on a formula prescribed by the government and reflects prices to the retail class of trade. In addition, each state Medicaid program had the ability to discern AMP from the various exchanges between the parties with respect to Abbott's Medicaid Rebate payments because the rebate is calculated as a percentage of AMP for this drug.
- Abbott also provided the Veterans Administration with pricing information reflecting the discounted pricing available to some of its largest customers in the

[71] See KYDMSPL1022491-98.

course of assisting the government in establishing the Federal Supply Schedule (FSS) pricing for Abbott's drugs.

- State Medicaid programs had visibility to transaction prices in the course of processing claims information. For example, many claims were submitted and paid at amounts below the AWP-based reimbursement, and reflected discounts available to certain pharmacies. In addition, some states required pharmacies to submit information regarding their actual acquisition cost.[72]
- State Medicaid programs had visibility to transaction prices through the administration of 340B/Public Health Service programs where the pharmacies were required to submit their actual acquisition costs to the state.
- The government had access to other market based pricing information (e.g., IMS Health).
- Many state Medicaid agencies determined their own state Maximum Allowable Cost ("MAC") to limit reimbursement of generic drugs.[73] MAC information was available across states.

B. Context for Spread Allegations

57) In my view it is important to put into context the purported size of the alleged spreads by looking at those spreads not in terms of a package but rather in terms of dollars per claim. The average difference per claim in Dr. Duggan's report is approximately $3.00.[74] The small alleged "DIFFERENCE" per claim highlights the sensitivity of his analysis due to the fact that minor changes in one part of the overall reimbursement can have a significant impact on Dr. Duggan's "DIFFERENCE".

58) For example, in context of the under reimbursement of dispensing fee as sited in the dispensing fee studies I previously mentioned, this $3.00 spread is much less than the underpayment of dispensing fees. As the expert calculating damages in

[72] See, e.g. HHD006-0060.

[73] See "Study of Medi-Cal Pharmacy Reimbursement" Prepared for the California Department of Health Services. Prepared by Myers and Stauffer, June 2002, page 6.

[74] See Duggan Dep. April 17, 2009 p. 155.

this case, Dr. Duggan should have considered this information to determine whether any excessive payment has been made.

C. CMS use of FUL

59) The 1987 CMS regulation on the FUL makes clear that the Federal government intended to allow a margin on ingredient cost reimbursement.[75] Dr. Duggan made no effort to investigate the impact of the FUL intended margin when creating his "Calculated Price". Even today in the Deficit Reduction Act of 2005, Congress acknowledges that a factor of 250% is necessary when using the Average Manufacturer Price to arrive at the Federal Upper Limit (FUL) reimbursement level for drugs.[76]

D. State Use of MAC Pricing

60) The drug at issue in this matter is included on many states' MAC lists.[77] States made individual determinations about the appropriate basis for and level of MAC pricing considering various factors. For example, payors establish MAC pricing at levels which optimizes generic drug substitution. Dr. Duggan made no effort to identify the basis used to determine the MAC price in each state; to analyze the various states' policies in establishing their MAC price; or to exclude those transactions not based upon Abbott's published prices.

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[75] PRD0035.006 See Federal Register Vol. 52 No. 147 dated July 31, 1987 p. 28648 – 26658.

[76] See 2005 Deficit Reduction Act.

[77] See Footnote 66.

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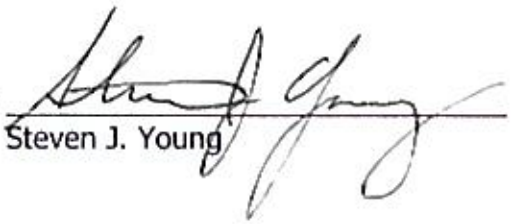
By: 
Steven J. Young